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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,695	PIERCE ET AL.	
	Examiner	Art Unit	
	KAJ K. OLSEN	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/15/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-16,18 and 21-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-16,18 and 21-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3, 6-16, 18, and 21-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Applicant has amended the independent claims to require the component providing the hydrophilic domains be "non-reactive". This is effectively a negative limitation excluding the use of any reactive agent (whatever that might mean) for providing this domain. However, applicant does not appear to have any support for a limitation excluding the use of reactive components for these domains. The only discussion of the use of these hydrophilic domains can be found at p. 5, ll. 7-15 and p. 20, ll. 23-28 of the specification. Neither of these sections discuss anything concerning these hydrophilic domains being non-reactive components. As MPEP 2173.05(i) makes clear, any negative limitation or exclusionary proviso must have a basis in the original disclosure and the mere absence of a positive recitation is not a basis for an exclusionary limitation. In other words, just because the specification never said these

hydrophilic domains were reactive doesn't permit the applicant to now claim that these domains are non-reactive.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3, 6-16, 18, and 21-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Because there is no support for the hydrophilic domains being "non-reactive" as discussed above, it is entirely unclear what the scope of this new limitation is. What constitutes a non-reactive component? Any material, including the PEG utilized by the present invention, is reactive depending on what it is to be reacted with. What is the threshold for when a particular material is deemed to be reactive and no longer within the scope of the claim? The specification is entirely unclear on this.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 3, 6-11, 29, 31, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (USP 6,103,033) in view of Mizutani et al (Bull. Chem. Soc. Jpn., 64, 1991, pp. 2849-2851) and/or Saby et al (Analytica Chemica Acta, 304, 1995, pp. 33-39).

9. Say discloses a biosensor for determining a concentration of an analyte in a liquid sample (e.g. glucose in blood) comprising an electrode support 50, an arrangement of electrodes (58, 60,

62) disposed on the electrode support, the arrangement of electrodes comprising at least one working electrode 58 and a second electrode (60, 62), the working electrode comprising conductive ink and at least one enzyme and mediator in it. See col. 20, ll. 10-29 where Say teaches placing the catalyst in the electrode ink and see col. 19, l. 43 - col. 20, l. 9 where Say considers the mediator to be part of the catalyst as well. Say discloses first and second conductive tracks 52 leading from the working and second electrode to an electrical contact 49. See fig. 11 for example. Say does not explicitly disclose the use of a polymer that provides a hydrophilic domain. Mizutani teaches that enzymes such as glucose oxidase (GOD) can lose their activity when incorporated into a hydrophobic carbon electrode, and teaches that combining the enzyme with a polymer such as polyethylene glycol (PEG) improves the activity of the enzyme. See fig. 2 and 3 and p. 2850. With respect to PEG creating hydrophilic domains, the present invention evidences that PEG is a hydrophilic polymer (claims 32 and 34 for example). Moreover, Mizutani teaches that the PEG-GOD complex is soluble in aqueous media (Results and Discussion on p. 2849). Saby further teaches that the PEG prevents the enzyme from denaturing in the carbon electrode (p. 34, par. 2). This reason is precisely analogous to the present invention's reason for adding the PEG hydrophilic domains, namely to provide a medium where the structure of the enzyme is not altered (p. 5, ll. 13-15). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of either Mizutani and/or Saby for the biosensor of Say so as to improve the activity of the enzyme in the conductive ink by allowing it to better dissolve into or to prevent it from denaturing in the carbon based ink of Say (col. 9, ll. 32-36).

10. With respect to the new limitation requiring these hydrophilic components to be non-reactive, because Mizutani and Saby are relying on the same material as disclosed by the present invention (i.e. PEG), the polymer of Mizutani and Saby is inherently non-reactive. Applicant's use of this new limitation appears to be motivated by the fact that the PEG of Mizutani and Saby would have to be made initially reactive via the use of a methoxy form of the PEG in order to form the PEG-GOD complex (see section 2.1 on pp. 34 and 35 of Saby for example). Whether or not this initial form of PEG constitutes the use of a reactive component (see 112 rejections above for a discussion of the clarity of the scope of this new limitation) does not alter the fact that once this PEG and GOD reaction are carried out, the finally formed product is presumably non-reactive for the unclear standards of the present invention. In other words, once the methoxy groups of the PEG are consumed in the reaction to form the product of PEG bonded to GOD, the remaining PEG left after the reaction would be just as non-reactive as the PEG of the present invention.

11. With respect to the mediator composition, the osmium complexes of col. 19, ll. 12-33 for example read on the defined organometallic and organic compounds of the claims.

12. With respect to the use of small sample volumes, see Say, col. 4, ll. 8-14.

13. With respect to the electrode spacing, see Say col. 11, ll. 22-36.

14. With respect to the electrode area, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize electrode areas of from 0.5 mm^2 to 5 mm^2, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In particular, larger electrodes would provide greater sensitivity while

smaller electrodes would hold the overall size of the sensor down. Finding the appropriate area that balances these competing concerns requires only routine skill in the art.

15. With respect to the presence of a third or trigger electrode, Say discloses a third electrode 62 (col. 14, ll. 44-50) and this would read on the defined third electrode. Although not disclosed as being a trigger electrode, the term "trigger" merely defines how applicant intends to utilize the electrode and does not further define the structure of the electrode itself.

16. With respect to the set forth fourth electrode, see Say fig. 6 and col. 14, ll. 29-43. With respect to the electrode having a trigger function, this again defines how the electrode is to be used and doesn't further define the structure of the electrode itself.

17. With respect to the use of dehydrogenase, see Say col. 19, ll. 43-55.

18. With respect to claim 31 (those limitations not covered above), Say discloses that the biosensor can be made to contact a meter (i.e. control unit). See col. 13, ll. 28-40.

19. Claims 1, 3, 6-11, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (USP 6,103,033) in view of Charlton et al (USP 5,798,031).

20. Say discloses a biosensor for determining a concentration of an analyte in a liquid sample (e.g. glucose in blood) comprising an electrode support 50, an arrangement of electrodes (58, 60, 62) disposed on the electrode support, the arrangement of electrodes comprising at least one working electrode 58 and a second electrode (60, 62), the working electrode comprising conductive ink and at least one enzyme and mediator in it. See col. 20, ll. 10-29 where Say teaches placing the catalyst in the electrode ink and see col. 19, l. 43 - col. 20, l. 9 where Say considers the mediator to be part of the catalyst as well. Say discloses first and second conductive tracks 52 leading from the working and second electrode to an electrical contact 49.

See fig. 11 for example. Say does not explicitly disclose the use of a polymer that provides a hydrophilic domain. Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Charlton for the sensor of Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Say would inherently create hydrophilic domains in the conductive ink.

21. With respect to the various dependent claims here, see the discussion of Say above.

22. Claims 1, 3, 6-16, 18 and 21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and either Mizutani and/or Saby.

23. Feldman discloses a biosensor (col. 1, ll. 13-14) having: an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and at least one reagent incorporated in the working electrode (col. 21 , ll. 28- 31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-

38). Feldman does not disclose placing the enzyme and the mediator into a conductive ink. Say (who has the same assignee as Feldman) discloses that in an effort to minimize leaching of the catalysts (i.e. the enzyme and mediator), the catalysts can be incorporated directly into the conductive ink of the sensor. See col. 19, l. 56 - col. 20, l. 29, especially col. 20, ll. 10-29. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Say for the biosensor of Feldman so as to obviate the need for multiple coating steps for the electrode as well as keeping the enzyme from leaching away. Keeping the mediator and enzyme from leaching away was a particular concern of Feldman (see abstract for example) and the suggestion of incorporating the enzyme and mediator into the conductive ink by Say represents an alternate or additional way to prevent such a leaching from occurring.

24. Neither Feldman nor Say explicitly disclose the use of a polymer that provides hydrophilic domains in the conductive ink. Mizutani teaches that enzymes such as glucose oxidase (GOD) can lose their activity when incorporated into a hydrophobic carbon electrode, and teaches that combining the enzyme with a polymer such as polyethylene glycol (PEG) improves the activity of the enzyme. See fig. 2 and 3 and p. 2850. With respect to PEG creating hydrophilic domains, the present invention evidences that PEG is a hydrophilic polymer (claims 32-34 for example). Moreover, Mizutani teaches that the PEG-GOD complex is soluble in aqueous media (Results and Discussion on p. 2849). Saby further teaches that the PEG prevents the enzyme from denaturing in the carbon electrode (p. 34, par. 2). This reason is precisely analogous to the present invention's reason for adding the PEG hydrophilic domains, namely to provide a medium where the structure of the enzyme is not altered (p. 5, ll. 13-15). It would

have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of either Mizutani and/or Saby for the biosensor of Feldman and Say so as to improve the activity of the enzyme in the conductive ink by allowing it to better dissolve into or to prevent it from denaturing in the carbon based ink of Say (col. 9, ll. 32-36).

25. With respect to the choice of mediator, see Feldman col. 15, ll. 20-25.

26. With respect to the use of a low volume, see Feldman col. 7, ll. 52-55.

27. With respect to the electrode spacing and area, see Feldman col. 24, ll. 66 and 67; col. 25, ll. 1-3; and col. 49, ll. 7 and 8.

28. With respect to the presence of a trigger electrode, Feldman discloses a biosensor wherein the electrode arrangement further comprises a trigger electrode (col. 50, ll. 60 and 61 and col. 51, ll. 1-12). Applicant discloses that a trigger electrode can be used to determine when the sample has been applied to the strip, thereby activating the assay protocol (p. 10, ll. 19-21). The trigger electrode prevents the assay from beginning until an adequate quantity of sample has filled the reaction zone (p. 10, ll. 22-24). Feldman discloses a sensor including a fill indicator, such as an indicator electrode, that can be used to determine when the measurement zone or sample chamber has been filled (col. 2, ll. 64-67). An indicator electrode is defined as one or more electrodes that detect partial or complete filling of a sample chamber and/or measurement zone (col. 7, ll. 3-5). Therefore, Feldman's indicator electrode is interpreted to be synonymous with trigger electrode.

29. With respect to the presence of a third and fourth electrode, see Feldman col. 49, ll. 19-21 and col. 51, ll. 37-45.

30. With respect to the set forth insulating layer, see Feldman col. 8, ll. 23-29 and fig. 4, element 40.

31. With respect to the set forth layer of mesh, see Feldman col. 29, ll. 47-54.

32. With respect to the set forth capillary, see Feldman col. 26, ll. 58-67 or fig. 5, element 26.

33. With respect to the set forth layer of tape, see fig. 2, element 30.

34. With respect to claims 16, 18, and 21-30 (those limitations not previously covered above), Feldman discloses a first substrate having two major surfaces (fig. 1, element 38 or fig. 3, element 38); a second substrate having two major surfaces (fig. 1, element 38 or fig. 3, element 38); where the working electrode is disposed on one major surface of the first substrate (col. 3, ll. 18 and 19, fig. 1, element 22 or fig. 3, element 22) while a second electrode is disposed on one major surface of the second substrate (col. 3, ll. 19 and 20, fig. 1, element 24 or fig. 3, element 24). Feldman further discloses an insulating layer disposed between said working electrode and said at least second electrode (col. 8, ll. 3-29, fig. 1, element 28 or fig. 3, element 28).

35. With respect to method claim 31 (those limitations not previously covered), Feldman teaches the use of a meter that contacts the leads of the sensor. See col. 35, ll. 27-61.

36. Claims 1, 3, 6-16, 18 and 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and Charlton.

37. Feldman discloses a biosensor (col. 1, ll. 13-14) having: an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); a first conductive track leading from the working

electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and at least one reagent incorporated in the working electrode (col. 21 , ll. 28- 31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38). Feldman does not disclose placing the enzyme and the mediator into a conductive ink. Say (who has the same assignee as Feldman) discloses that in an effort to minimize leaching of the catalysts (i.e. the enzyme and mediator), the catalysts can be incorporated directly into the conductive ink of the sensor. See col. 19, l. 56 - col. 20, l. 29, especially col. 20, ll. 10-29. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Say for the biosensor of Feldman so as to obviate the need for multiple coating steps for the electrode as well as keeping the enzyme from leaching away. Keeping the mediator and enzyme from leaching away was a particular concern of Feldman (see abstract for example) and the suggestion of incorporating the enzyme and mediator into the conductive ink by Say represents an alternate or additional way to prevent such a leaching from occurring.

38. Neither Feldman nor Say explicitly disclose the use of a polymer that provides hydrophilic domains in the conductive ink, Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. It would have

been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Charlton for the sensor of Feldman and Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Feldman and Say would inherently create hydrophilic domains in the conductive ink.

39. With respect to the various dependent claims, see the discussion of Feldman and Say above.

40. Claims 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say in view of Charlton as set forth for claims 1 and 31 above, and in further view of Yamashita et al (USP 5,472,590).

41. Say and Charlton set forth all the limitations of claims 32 and 34, but did not explicitly recite the use of polyethylene glycol as the hydrophilic polymer. However, polyethylene glycol is a subset of the broader polymer class of polyethylene oxide utilized by Charlton. In particular, polyethylene glycol is polyethylene oxide where the terminal groups of the polymer are hydroxyl units. Yamashita explicitly teaches that polyethylene glycol is a particular useful choice of polyalkylene oxide polymer when the property being desired is a hydratable substance (i.e. "water-keeping property"). See abstract and col. 5, ll. 51-63 of Yamashita. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the polyethylene glycol as taught by Yamashita for the polyethylene oxide suggested by Charlton for the biosensor of Say and Charlton because polyethylene glycol has been demonstrated as being a suitable choice of hydratable polyethylene oxide for sensor applications.

42. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and Charlton as set forth for claims 1, 16, and 31 above, and in further view of Yamashita.

43. The references set forth all the limitations of claims 32-34, but did not explicitly recite the use of polyethylene glycol as the hydrophilic polymer. However, polyethylene glycol is a subset of the broader polymer class of polyethylene oxide utilized by Charlton. In particular, polyethylene glycol is polyethylene oxide where the terminal groups of the polymer are hydroxyl units. Yamashita explicitly teaches that polyethylene glycol is a particular useful choice of polyalkylene oxide polymer when the property being desired is a hydratable substance (i.e. "water-keeping property"). See abstract and col. 5, ll. 51-63 of Yamashita. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the polyethylene glycol as taught by Yamashita for the polyethylene oxide suggested by Charlton for the biosensor of Feldman, Say, and Charlton because polyethylene glycol has been demonstrated as being a suitable choice of hydratable polyethylene oxide for sensor applications.

Response to Arguments

44. Applicant's arguments filed 6/15/2009 have been fully considered but they are not persuasive. With respect to the rejections relying on Say in view of Mizutani or Saby, applicant urges that these references are not combinable when taken as a whole. In particular, applicant urges that Say discloses that the catalyst (which would include the enzyme) is preferably non-leachably disposed on the sensor, while Mizutani and Saby both suggest that the enzymes leak out of their disclosed electrodes. This is unpersuasive for a number of reasons.

45. First, there is nothing in Mizutani or Saby to suggest that the addition of the PEG domains to the electrodes negatively impacted how much the enzyme tends to leak out of the electrode. In particular, Mizutani states that both the unmodified and modified electrodes (i.e. CPE I and CPE II respectively) exhibited this same leaching behavior and only stated that this leaking problem "was not improved by a modification of the enzyme." Saby only stated that the lost of current was attributed to the lost of the enzyme and gave no indication that this lost was any more or less than what one would have seen without the PEG modification. If the addition of the PEG domains significantly improved the activity of the enzyme (see Mizutani and Saby and the previous the 2/02/2009 rejection (reprinted above)) and did not negatively impact the leaching problem, then there is nothing in Mizutani or Saby that is teaching away from the desired non-leachability of Say.

46. Second, even if the examiner were somehow persuaded that the polymer of Mizutani or Saby negatively impacted the leachability of the enzyme, Mizutani further urges that this leaching problem can be solved by the incorporation of a coating over the electrode (p. 2851, last sentence of col. 1), which is very similar to one of the suggestions Say had for achieving the desired non-leachability (i.e. providing one or more barrier membrane or films to contain the catalysts (col. 19, ll. 59-67)). Hence, even though the hydrophilic domains were not the cause of the enzyme leaching (see the discussion above), Mizutani already suggested that there was a solution to this leaching that would be precisely germane to the teaching of Say.

47. Third, Say already disclosed how to make its enzyme non-leachable for the col. 20 embodiment of its sensor. In particular, Say disclosed utilizing the addition of a curable binding to the catalyst and carbon ink mixture (col. 20, ll. 15-29). Contrast this with Mizutani and Saby

where their enzyme/carbon combination was simply mixed together with no apparent binding agent (see Mizutani last paragraph of "Experimental" on p. 2849 and Saby section 2.3 on p. 35). Hence, it is improper to compare the leaching behavior or Mizutani or Saby with the desired non-leachability of Say when neither Mizutani nor Saby incorporated binding agents within their electrodes which presumably would have prevented leaching whether the enzyme were PEG modified or not. The examiner never suggested in the 2/2/2009 rejection (reprinted above) that the entire electrode of Mizutani or Saby be substituted for the electrode of Say, but only that it would have been obvious to incorporate the PEG modified enzyme of Mizutani or Saby for the unmodified enzyme of Say to achieve greater activity of the enzyme.

48. Applicant urges that the proposed modification to Say with Mizutani or Saby would render the prior art invention unsatisfactory for its intended use. Applicant's main point for this allegation is the fact that the enzyme of Say is heated during the manufacture of the sensor and the enzyme of Mizutani or Saby might denature during this heating process. This is also unpersuasive for a number of reasons. First, this argument is pure speculation by the applicant as they have not provided any evidence suggesting that this would be the case. Second, the enzymes relied on by Say include glucose oxidase which Say evidences is "thermostable" (col. 20, ll. 40-43). Glucose oxidase is the same enzyme being relied on by both Mizutani and Saby. It is entirely unclear why applicant speculates that the enzyme of Mizutani or Saby would not be able to withstand this heating process, when the enzyme of Mizutani and Saby is the same thermostable enzyme being utilized already by Say. Third, the cited passage of Say (col. 31, ll. 39-42) is drawn to this heating step is a step for cross-linking the various component of the catalyst together. As Say made clear in col. 19, ll. 56-67, cross-linking is only one of many ways

of making the catalyst non-leachable. Hence, there is nothing in Say to suggest this heating step is even a mandatory step for constructing the sensor. For example, Say discloses that the catalyst can be made non-leachable by use of a curing agent and the curing agent need not be heat activated, but could be UV activated or based on the mere evaporation of a solvent (col. 20, ll. 15-29). Hence, there is no requirement for a heating step for Say and the issue of whether the enzymes of Mizutani and Saby could withdrawn that optional heating step is irrelevant.

49. With respect to the arguments concerning whether the domains of Mizutani and Saby constitute "non-reactive components", see the discussion of this new limitation both in the 112 rejections as well as in the modified art rejection above.

50. With respect to applicant's arguments concerning the continued use of Charlton in the rejections above, applicant repeatedly refers to and relies on information contained with Appendix A of Skoog et al, which applicant states was being provided. However, applicant does not appear to have provided said teaching and the examiner cannot appropriately respond to any of these arguments relying on Skoog when such teaching that has not been presented to the examiner.

51. Applicant's remaining arguments concerning the rejections relying on Feldman as a primary teaching appear to rely on the perceived failings of the earlier teachings of Mizutani, Saby, or Charlton. Because the examiner did not find these earlier arguments persuasive, these further arguments are similarly unpersuasive.

Conclusion

52. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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